REMARKS

Applicants have carefully studied the Office Action mailed on December 2, 2003, which issued in connection with the above-identified application. The present response is intended to be fully responsive to all points raised by the Examiner. Favorable reconsideration and an early action on the merits is respectfully requested.

Claims 1-33 are pending and at issue in this application.

In the Action, the Examiner required restriction to one of the following groups of claims under 35 U.S.C. § 121:

Group I: claims 1-8 drawn to an isolated Ozz protein;

Group II: claims 9-17 and 19-21 drawn to an isolated nucleic acid encoding an Ozz protein, a vector, a host cell, and a method of producing an Ozz protein;

Group III: claim 18 drawn to non-human animal transformed with a vector comprising a nucleic acid encoding a fragment of an Ozz protein;

Group IV: claims 22 and 23 drawn to an *Ozz* muscle-specific promoter;

Group V: claim 24 drawn to an antibody;

Group VI: claim 25 drawn to a method for detecting an Ozz protein using an antibody;

Group VII: clams 26-28 drawn to a method for detecting expression of *Ozz* mRNA;

Group VIII: claims 29 and 30 drawn to a method for detecting damage to muscle tissue comprising detecting an increase in the level of Ozz protein;

Group IX: claims 31-33 drawn to a method for detecting a disease associated with a defect in Ozz expression.

In the Action, the Examiner contends that each of the designated groups represents a patentably distinct invention and requests to elect a single group of claims. The Examiner further requests to elect one sequence species selected from the group consisting of SEQ ID NOS: 1-5, 7, 9, 11, 19, and 21-24[1].

In order to be fully responsive to the Requirement for Restriction, applicants hereby elect, with traverse, to prosecute the claims of Group II (claims 9-17 and 19-21). Applicants further elect, with traverse, a murine *Ozz* nucleotide (cDNA) sequence, SEQ ID NO: 1.

Although applicants are making the above election to be fully responsive to the Requirement for Restriction, applicants respectfully traverse the Requirement and reserve the right to petition therefrom under 37 C.F.R. § 1.144. In particular, applicants respectfully request reconsideration and modification of the Restriction Requirement to allow prosecution of the claims of Groups I, II and VII or at least the claims of Groups I and II in the same application, for the reasons provided as follows.

Under 35 U.S.C. § 121, "two or more independent and distinct inventions . . . in one application may . . . be restricted to one of the inventions". Inventions are "independent" if there is no distinct relationship between the two or more subjects disclosed" (MPEP 802.01). The term "distinct" means that "two or more subjects as disclosed are related . . . but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER" (MPEP 802.01, July 1988) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification;

2. Separate status in the art; or,

3. Different field of the search.

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[1] Applicants respectfully note that, in the species election requirement, the Examiner has omitted SEQ ID NO: 20, which is listed together with SEQ ID NOS: 19 and 21-24 in claim 8. Correction is respectfully requested.

Moreover, according to Patent Office examining procedures, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803) (emphasis added).

Applicants respectfully submit that, in contrast to the Examiner's assertion, the claims of Groups I (directed to an Ozz protein), II (directed to a nucleic acid encoding an Ozz protein, a vector, a host cell, and a method of producing an Ozz protein) and VII (directed to a method for detecting expression of Ozz comprising detecting *Ozz* mRNA) contain multiple unifying features and the search of the features of these claims would be necessarily co-extensive.

At page 2 of the Office Action, the Examiner states that the inventions of Groups I and II are unrelated, because each of the products of Groups I and II are independent chemical entities and require different literature searches. Applicants respectfully disagree and note that a search of the amino acid sequences, which are similar or identical to the Ozz protein sequences recited in claims of Group I would necessarily and unescapably require a search of the nucleic acid sequences, which are similar or identical to the nucleic acid sequences recited in the claims of Group II (*e.g.*, SEQ ID NOS: 1 and 3). Indeed, claim 9 (Group II) recites an isolated nucleic acid encoding the Ozz protein of claim 1 (Group I), and claim 6 (Group I) recites the Ozz protein encoded by SEQ ID NO: 1 which is recited in claim 14 (Group II). Also, claims 15-17 and 19 (Group II) encompass vectors encoding Ozz proteins recited in the claims of Group I, host cells transfected with such vectors, and a method for producing Ozz proteins using such vectors and host cells.

At page 3 of the Office Action, the Examiner states that, although the invention of Group II is related to the invention of Group VII as product and process of use, the product of Group II (nucleic acid) can be used in a materially different process (*e.g.*, a recombinant production of Ozz protein). In response, applicants note that, as recited in claims 27 and 28 (Group VII), the method for detecting expression of *Ozz* mRNA can be practiced only using *Ozz*-specific nucleic acids recited in the claims of Group II (see, in particular, claims 9-10 and 20-21). Indeed, claims of Groups II and VII are classified in the same search class (class 435).

In light of the foregoing arguments, it can be concluded that the claims of provisionally elected Group II contain multiple unifying features with the claims of Groups I and VII. Hence, it is believed that a single search of the features of the claims of Group II would necessarily and inescapably require a search of the subject matter of the claims of Groups I and VII. The claims of Groups I, II and VII represent a web of knowledge and continuity of effort that merits examination in a single application. The search and examination of each group is necessarily co-extensive, and in any event would involve such interrelated art that the search and examination of the Groups I, II and VII can be made without undue burden on the Examiner. Accordingly, applicants respectfully request that the Examiner modifies the Requirement to allow prosecution of Groups I, II and VII or at least Groups I and II together in the same application.

For the record, applicants also note that, in contrast to the Examiner's assertion, claims of Group V (claim 24) and VI (claim 25) also share patentability issues as they are directed to an anti-Ozz antibody and a method for detecting an Ozz protein using such antibody, respectively. Indeed, claim 25 refers back to claim 24.

The Examiner's requirement to elect a single sequence species is also traversed. Applicants respectfully note that, SEQ ID NO: 1 is a murine *Ozz* cDNA sequence which encodes a murine Ozz protein having SEQ ID NO: 2. Similarly, SEQ ID NO: 3 is a human *Ozz* cDNA sequence which encodes a human Ozz protein having SEQ ID NO: 4 (see, *e.g.*, Figures 2A-B and 4). As shown in Figures 3 and 4 and specified, *e.g.*, at page 38, lines 16-25 of the present specification, murine and human Ozz sequences (both nucleotide and protein) are highly homologous. It follows, that a search for any one of the sequences among SEQ ID NOS: 1-4 would necessarily and unescapably require a search of all other sequences. Most importantly, SEQ ID NOS: 5, 7, 9, 11, and 19-24 simply represent various fragments of an Ozz protein (see, *e.g.*, Figure 6 and page 8, lines 16-30 of the present specification). It follows, that a search for any one of the sequences among SEQ ID NOS: 5, 7, 9, 11, and 19-24 would necessarily and unescapably require a search of the full-length Ozz protein sequences such as SEQ ID NOS: 2 and 4 and their encoding *Ozz* nucleic acid sequences such as SEQ ID NOS: 1 and 3.

Furthermore, as specified in MPEP 803.04 (emphasis added): "to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden

on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996). It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together."

In light of the foregoing practice and arguments, it is believed that, in addition to the provisionally elected SEQ ID NO: 1, the applicants are entitled to election of all sequences comprising SEQ ID NOS: 1-5, 7, 9, 11, and 19-24.

CONCLUSION

Applicants request entry of the foregoing remarks in the file history of this application. In view of the above arguments, reconsideration and modification of the Requirement for Restriction is respectfully requested, and an early action on the merits is courteously solicited. If the Examiner believes that a telephone conversation would help advance the prosecution in this case, the Examiner is respectfully requested to call the undersigned agent at (212) 527-7634. The Examiner is hereby authorized to charge any additional fees associated with this response to our Deposit Account No. 04-0100.

Respectfully submitted,

Dated: December 23, 2003

Irina E. Vainberg, Ph.D.

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